

Exhibit B



Office of the Chief Counsel
Food and Drug Administration
10903 New Hampshire Avenue
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November 26, 2019

Via Email

John C. Bostic
Assistant United States Attorney
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Kevin Downey
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Jeffrey B. Coopersmith
Orrick, Herrington & Sutcliffe, LLP
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Re: *United States v. Elizabeth Holmes & Ramesh Balwani*, 18-CR-00258 EJD
(N.D. Cal.)

Dear Messrs. Bostic, Downey, and Coopersmith:

Pursuant to the Court's November 5, 2019 Order, I write regarding FDA's investigation into (a) production of hard copy documents and (b) the partially visible emails from Alberto Gutierrez's custodial file.

Hard Copy Documents

Following the Court's November 5, 2019 Order, I reached out to the custodians currently employed by FDA to ask them to confirm that they had already identified and provided all potentially responsive hard copy documents. To date, I have confirmed that the majority of active custodians either already identified and provided all potentially responsive hard copy documents, did not have any, or have since provided all potentially responsive hard copy documents to my office. A minority of active custodians have not responded to me, so I will continue to follow up with them. FDA will produce all responsive and non-privileged hard copy documents to the parties.¹

Following the November 5 Order, I also coordinated calls with the records liaison officers for each FDA Center that had responsive records to determine whether hard copy materials were retained for former FDA employees (to the extent they were not

¹ As you know, FDA participated in a meet-and-confer with the parties on Friday, November 22, 2019, and is aware of ongoing discussions among the parties about obtaining a court order and/or protective order that would permit FDA to provide documents to the Department of Justice for it to conduct a responsiveness review and produce those responsive documents to Defendants without redactions. Should the parties obtain the discussed court order and protective order, it might affect the timeline when the documents discussed in this letter are produced and the entity by whom they are produced (i.e., DOJ).



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previously electronically scanned), and where such records were stored. I was informed that individual supervisors should have former employees' hardcopies, if any, and I am currently in the process of identifying and contacting the relevant supervisors. Should this investigation result in the identification of responsive hard copy documents that do not otherwise exist electronically, FDA will collect them and produce them to the parties to the extent they are responsive and not privileged.

Gutierrez Emails

As explained in FDA's October 9 and 30, 2019 letters to the parties, as well as during our October 23, 2019 meet-and-confer call, approximately 1,114 Alberto Gutierrez emails are only partially visible. Prior to the November 4, 2019 hearing before the Court, I was informed by FDA's e-discovery team that the partially visible emails were due to a damaged email container file (i.e., corrupt PST) that could not be fixed. FDA explained this to the Court at the November 4, 2019 hearing. Despite defense counsel's accusations at the hearing of malfeasance on the part of Mr. Gutierrez and/or FDA, FDA's subsequent investigation confirmed what it had earlier communicated.

Specifically, FDA's e-discovery team confirmed that the PST file containing Mr. Gutierrez's email was damaged and could not be repaired by any tools available to FDA. Indeed, the partially-visible emails (and some fully-visible emails) in Mr. Gutierrez's custodian file were the extent of what FDA's e-discovery team was able to recover from the damaged PST file by using recovery software available to it. FDA's e-discovery team additionally relayed that the creation of the PST file from Mr. Gutierrez's emails at the time of his departure was an automated process run by a technical script, and that no errors were reported by the script for Mr. Gutierrez's file. The e-discovery team was thus unable to determine whether the PST file became damaged at the time of its creation (despite the lack of script error notification) or at some subsequent time. Moreover, the e-discovery team was able to confirm that there is no evidence or indication that the damaged PST file is the result of any action or inaction by Mr. Gutierrez or anyone else at FDA.

FDA will produce all responsive and non-privileged full versions of Mr. Gutierrez's email that it is able to identify among other custodians' files and, where it is unable to find a full version, will produce the partially-visible emails from Mr. Gutierrez's custodial file to the extent they have not already been produced.

I trust that the above information satisfies FDA's obligations to disclose the procedures and results of FDA's investigation into its production of hard copy documents and the damaged PST file from Mr. Gutierrez's custodial file.

Sincerely,

Marci B. Norton

Marci B. Norton
Senior Counsel